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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,794	12/27/2001	Yasuo Komatsu	033808/0272544	7169

7590

10/21/2003

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EXAMINER
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ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

**Office Action Summary**

Application No.

10/032,794

Applicant(s)

Komatsu et al

Examiner

Jane Zara

Art Unit

1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Dec 27, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-21 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

File

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### **DETAILED ACTION**

Claims 1-21 are pending in the instant application.

#### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, 8-10, drawn to compositions comprising hairpin ribozymes exhibiting a complex structure with an oligonucleotide of formula I or II, classified in class 536, subclass 24.5.
- II. Claims 1-4, 6-10, drawn to compositions comprising hairpin ribozymes exhibiting a complex structure with an oligonucleotide of formula III, classified in class 536, subclass 24.5.
- III. Claims 11 and 12, drawn to a method of activating a hairpin ribozyme, classified in class 435, subclass 91.31.
- IV. Claims 13-16, drawn to a method of detecting a target nucleotide sequence, classified in class 435, subclass 6.
- V. Claim 17, drawn to a detection kit for a target nucleotide sequence in a sample, classified in class 536, subclass 24.5.
- VI. Claims 18-21, drawn to a method of cleaving a ribonucleotide sequence, classified in class 435, subclass 91.1.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I, II, V and III, IV, VI are patentably distinct. Inventions I-VI are related because they comprise patentably distinct inventions drawn to compositions comprising hairpin ribozymes, methods of using, and methods of activating hairpin ribozymes. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The compositions of Groups I (compositions comprising hairpin ribozymes exhibiting a complex structure with an oligonucleotide of formula I or II), II (compositions comprising hairpin ribozymes exhibiting a complex structure with an oligonucleotide of formula III), and V (a detection kit for a target nucleotide sequence in a sample) are not required for the methods of Groups III (a method of activating a hairpin ribozyme), IV (a method of detecting a target nucleotide sequence) and VI (a method of cleaving a ribonucleotide sequence). The operation, function and effects of the compositions of Groups I, II and V are completely different and distinct from the operation, function and effects of the methods of Groups III, IV and VI. Therefore, the inventions of these different and distinct groups are capable of supporting separate patents.

Inventions I and II and V are patentably distinct. Inventions I, II and V are related because they comprise compositions and kits comprising hairpin ribozymes. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and

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they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the compositions comprising hairpin ribozymes exhibiting a complex structure with an oligonucleotide of formula I or II (Group I), the compositions comprising hairpin ribozymes exhibiting a complex structure with an oligonucleotide of formula III (Group II) and the detection kit for a target nucleotide sequence in a sample (Group III) are chemically, biologically, structurally and functionally distinct from each other and thus one does not render the other obvious. The ribozymes of Groups I or II are not required to produce each other, or to produce the kit of Group V, and the kit of Group V is not required to produce the ribozymes of Groups I or II. Therefore, the inventions of these different Groups are capable of supporting separate patents.

Inventions III and IV and VI are patentably distinct. Inventions III and IV and VI are related because they comprise methods of using activating hairpin ribozymes, methods of detecting nucleotide sequences comprising hairpin ribozymes and methods of cleaving a ribonucleotide sequence comprising hairpin ribozymes. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups III, IV and VI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups III (activating a hairpin ribozyme), IV (method of detecting a target nucleotide sequence) and VI (cleaving a ribonucleotide sequence) comprise steps which are not required for or present in the

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methods of each other's Groups. Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions I-VI are related as indicated above, because they comprise patentably distinct inventions drawn to compositions, methods of using, and methods of activating hairpin ribozymes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

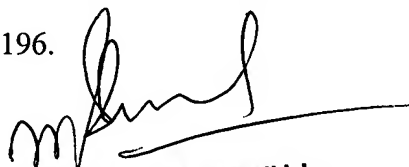
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER

***JZ***

October 19, 2003